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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/575,307	05/19/00	BROVELLI E	3086/1154 (P

000757 HM22/0717
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EXAMINER	
MELLER,M	
ART UNIT	**PAPER NUMBER**
1651	6

DATE MAILED: 07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/575,307	Applicant(s) BROVELLI ET AL.	
	Examiner Michael V. Meller	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 1-6 and 12-16 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

On page 3 of the specification, it is recommended that applicant change, "SUMMARY" to "SUMMARY OF THE INVENTION" to make it clearer that this is the summary of the invention.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 12-14, drawn to an extract of *Echinacea*, classified in class 424, subclass 737, for example.

II. Claims 7-11, drawn to a method of using said extract, classified in class 424, subclass 773, for example.

III. Claims 15 and 16, drawn to a method of making said extract, classified in class 424, subclass 725, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made in a materially different process such as genetic engineering.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as treating urinary tract infections.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Donna Becker on 2/23/2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 7-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-6 and 12-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms, "lipid-soluble" (claims 7, 9 and 11) and "chloroform soluble" (claims 9 and 11) are vague and indefinite terms. It is not clear if the extract is extracted with a lipid or chloroform or if the extract is soluble in a lipid or chloroform. How is the extract soluble in a lipid ? This is not explained in the specification. In other words, the terms do not describe the metes and bounds of the meaning of these terms. Further, the terms are relative. Many extracts can be a little soluble in a lipid or chloroform. The claims need to be more definite in their meaning. (Please note lipids constitute numerous fat compositions including fats, waxes, short chain fatty acids, etc.). The other claims are rejected since they depend on rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menon et al. (Menon) in view of Kass et al. (Kass), Dorland's Illustrated Medical Dictionary (Dorland), The Condensed Chemical Dictionary (Condensed) and Braswell et al. (Braswell)

Menon teaches that an *Echinacea* extract powder has been observed as inducing the activity of Phase II enzymes, which have a detoxifying effect on potential carcinogens in the human body, see col. 2, lines 41-55. Menon does not teach administering the extract to a subject, that the extract is lipid and/or chloroform soluble and that the extract is extracted from the roots or aerial parts of the plant.

Kass teaches that *Echinacea* extract can be administered to a subject for treating cancer, see abstract, col. 2, lines 40-55, col. 2, line 65-col. 3, line 3, and the claims. Further, Kass teaches that an alcohol such as ethyl alcohol can be used to extract such an herbal.

Dorland teaches that a lipid is extractable (soluble) in alcohols, see page 943.

Condensed teaches that chloroform is miscible with alcohol, see page 237.

Braswell teaches that in over 350 studies of *Echinacea* extracts, extracts from both root and aerial parts are commonly used, see col. 2, lines 30-50 and the claims. Further, Braswell teaches that since the extract activates the immunological system, it is believed that *Echinacea* extracts may also provide some effects against tumors, see col. 2, lines 61-65.

Thus, it would have been obvious to one of ordinary skill in the art to extract the extract of Menon with alcohol since Kass teaches that *Echinacea* is routinely extracted with ethyl alcohol and it is inherent to the properties of alcohol that such extracts yielding therefrom would be lipid and chloroform soluble as taught by Condensed and Dorland.

Further, to administer the extract to induce the expression of a phase II enzyme in a subject would also have been obvious since Menon teaches that such extracts induce the activity of Phase II enzymes and that such enzymes have a detoxifying effect on potential carcinogens in the human body. Also, since Kass teaches administering such an extract to treat cancer, then it would have been clearly obvious that one of ordinary skill in the art would know to give such an extract to a patient in an effort to use the extract as an anti-cancer drug since this is the intended purpose of inducing the expression of phase II enzymes as taught by Menon.

Also, since Braswell teaches that *Echinacea* extracts from root or aerial parts are both commonly used, then it would clearly have been within the purview of the skilled artisan to use either the root or the aerial parts for extraction from the *Echinacea* of Menon.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 10:30am-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM

July 16, 2001

Michael Meller
Patent Examiner
Art Unit 1651